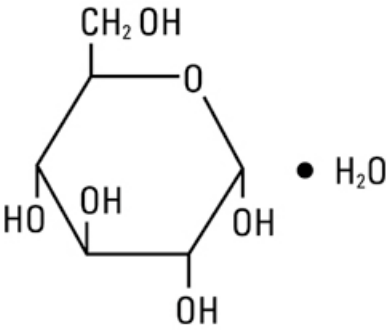
**ALCOHOL IN DEXTROSE - alcohol and dextrose hydrous injection, solution**
HOSPIRA, INC.

$R_x$ only

## DESCRIPTION

5% Alcohol in 5% Dextrose Injection, USP is a sterile, nonpyrogenic, hypertonic solution of ethyl alcohol and dextrose in water for injection, intended for intravenous administration.
Each 100 mL contains dehydrated alcohol 5 mL and dextrose, hydrous 5 g in water for injection; osmolar concentration 1104 mOsmol/liter (calc.); pH 4.5 (3.5 to 6.5). The solution provides a total of 450 calories/liter (alcohol 280; dextrose 170).*
The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose injection. When smaller doses are required the unused portion should be discarded.
5% Alcohol in 5% Dextrose is a parenteral fluid and nutrient replenisher.
Dehydrated Alcohol, USP is chemically designated as ethanol or ethyl alcohol ($CH_3CH_2OH$), a clear, colorless, mobile, volatile liquid miscible with water.
Dextrose, USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. It has the following structural formula:




Water for Injection, USP is chemically designated $H_2O$.

## CLINICAL PHARMACOLOGY

Intravenously administered 5% Alcohol in 5% Dextrose Injection, USP provides a source of water and carbohydrate calories. In the average adult, pure ethyl alcohol is metabolized at a rate of approximately 10 to 20 mL per hour, depending on body weight and tolerance of the individual. (This is equivalent to an intravenous rate of infusion of 200 to 400 mL per hour of a 5% alcohol solution). Sedative effects of alcohol occur if the rate of infusion exceeds the rate of metabolism. Dextrose can be infused at a maximum rate of 0.5 g/kg of body weight/hr without producing glycosuria (equivalent to 700 mL of a 5% dextrose solution for a 70 kg adult). Thus, the maximum rate that alcohol can be infused without producing sedative effects is well below the maximum rate of utilization of dextrose.
Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action.
Alcohol is metabolized, mostly in the liver, to acetaldehyde or acetate. The rate of oxidation is a linear function of time. Starvation lowers the rate of metabolism and insulin increases the rate.
Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.
* Caloric value based on 5.6 calories/mL of alcohol and 3.4 calories/g of dextrose (International Critical Tables, V, p. 166, 1929).
Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirements range from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium ion ($Na^+$) plays a major role in maintaining physiologic equilibrium.

## INDICATIONS AND USAGE

5% Alcohol in 5% Dextrose Injection, USP is indicated for parenteral replenishment of fluid and carbohydrate calories, especially to increase caloric intake in patients whose oral intake is restricted or inadequate to maintain nutritional requirements.

## CONTRAINDICATIONS

Alcohol should not be used in patients with epilepsy or urinary tract infection. 5% Alcohol in 5% Dextrose Injection, USP is contraindicated in diabetic coma.
Alcohol is contraindicated in patients who have been addicted to it.
Do not give subcutaneously and avoid extravasation during intravenous administration.

**WARNINGS**
Alcohol should be used cautiously, if at all, in patients with liver impairment, in the presence of shock, following cranial surgery, in actual or anticipated postpartum hemorrhage or in the presence of significant renal impairment.
Alcohol will decrease blood sugar in diabetic patients. In the untreated diabetic the rate of alcohol metabolism will be slowed.
As a nutrient, alcohol supplies only calories. Given alone, it may cause or potentiate vitamin deficiencies and disturbances of liver function.
Alcohol crosses the placenta rapidly and enters the fetal circulation. It may also be found in the milk of lactating women. The use of this preparation in pregnancy should be carefully deliberated.
The intravenous administration of this solution can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

**PRECAUTIONS**
5% Alcohol in 5% Dextrose Injection, USP should be administered slowly, and the patient observed for restlessness or narcosis.
The half-lives of diphenylhydantoin, warfarin and tolbutamide may be shortened by 50 to 75% by concurrent administration of alcohol.
Alcohol increases serum uric acid and can precipitate acute gout.
The vasodilating effect may potentiate postural hypotension, particularly in association with some antihypertensive drugs.
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.
Do not administer unless solution is clear and seal is intact. Discard unused portion.

**Pregnancy Category C.**
Animal reproduction studies have not been conducted with alcohol or dextrose. It is also not known whether alcohol or dextrose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Alcohol and dextrose should be given to a pregnant woman only if clearly needed. See WARNINGS.

**Pediatric Use**
The safety and effectiveness of 5% Alcohol in 5% Dextrose Injection, USP have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

**Drug Interactions**
Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

**ADVERSE REACTIONS**
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
Alcoholic intoxication may occur with too rapid infusion. Vertigo, flushing, disorientation (especially in elderly patients), or sedation may also occur. An alcoholic odor may be noted on the breath. Generally, these effects can be avoided by slowing the rate of infusion.
Too rapid infusion of hypertonic solutions may cause local pain and rarely, excessive vein irritation. Use of the largest available peripheral vein and a small bore needle is recommended.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

**DRUG ABUSE AND DEPENDENCE**
Abuse of ingested alcohol is well known, including alcohol dependence due to addiction. Abuse of parenterally administered alcohol is not known or considered to pose a potential problem of dependence or addiction.

**OVERDOSAGE**
In the event of alcoholic intoxication or sedation, the infusion should be slowed or temporarily discontinued. If overhydration or solute overload occurs, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS, PRECAUTIONS and ADVERSE REACTIONS.

**DOSAGE AND ADMINISTRATION**
5% Alcohol in 5% Dextrose Injection, USP should be administered by slow intravenous infusion. Administration of 200 mL per hour will produce a blood level of less than 0.08 g of alcohol per 100 mL of blood. A normal adult can metabolize 10 mL of alcohol per hour (equivalent to 200 mL of a 5% alcohol solution).
The adult dosage ranges from 1 to 2 liters/day (24 hours) as determined by the needs of the patient. The average adult daily fluid requirement of 3 liters/day should be provided by other suitable solutions to meet daily maintenance requirements for electrolytes.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

**HOW SUPPLIED**

5% Alcohol in 5% Dextrose Injection, USP is supplied in a single-dose 1000 mL glass container (List No. 1500).
**Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]**

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